

Office Action Summary

Application No.
09/203,676

Applicant(s)

Zalutsky

Examiner

Karen Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) 22-43 is/are withdrawn from consideration.

☒ Claim(s) 5-7, 9, and 10 is/are allowed.

☒ Claim(s) 1-4, 8, 11-21, and 44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

1. Claims 1-3 have been amended. Claim 44 has been added. Claims 1-21 and 44 are under consideration.

New Rejections

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 8, 11-21 and 44 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ligands consisting of antibodies, does not reasonably provide enablement for ligands consisting of fragments of antibodies or synthetic peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims 1-4, 8, 11-21 and 44 are broadly drawn to a composition comprising a ligand which binds to a surface antigen selected from the group consisting of an antibody, a fragment of an antibody and a synthetic peptide; an oligopeptide comprising a positively charged amino acid residue, not comprising more than two contiguous L-amino acids, said oligopeptide not binding to the surface antigen; and a label which is covalently bound to the oligopeptide. The specification teaches radio labeled SEQ ID NO:3 covalently bound to an anti-EGFRviii, L8A4, and radio labeled SEQ ID NO:3 covalently bound to a chimeric anti-EGFRviii, chL8A4. The specification does not teach radio labeled oligopeptide, covalently bound to a small antibody fragment, such as a CDR domain or the Fc portion of an antibody, or teach radio labeled oligopeptide covalently bound to a synthetic polypeptide. It is well known in the art that polypeptides are folded 3-dimensional structures, the function and stability of which are directly related to a specific conformation (Mathews and Van Holde, Biochemistry, 1996, pp. 165-171). In any given protein, amino acids

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distant from one another in the primary sequence may be closely located in the folded, 3-dimensional structure (Mathews and Van Holde, Biochemistry, 1996, pp. 166, figure 6.1). The specific conformation of a protein results from non-covalent interactions between amino acids, beyond what is dictated by the primary amino acid sequence. Thus, it could not be predicted what effect the covalent attachment of a oligopeptide of undisclosed length would exert on the three dimensional structure of a small antibody fragment or a synthetic peptide. There are no teachings regarding how to avoid the disruption of non-covalent interactions in a small antibody fragment or a synthetic polypeptide, the shape of which is critical for binding to a specific surface antigen, when contemplating the attachment of an oligopeptide. One of skill in the art would not be able to predict if non-covalent interactions between the bound oligopeptide and the ligand consisting of a small antibody fragment or a synthetic polypeptide, would result in an alteration of the shape of the ligand thus interfering with the unique three-dimensional structure of the ligand and therefore the ability of the ligand to bind the specific surface antigen. In addition, Bowie et al (Science, 1990, 257:1306-1310) teaches that the problem of predicting protein/polypeptide structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). For these reasons, one of skill in the art would be forced into undue experimentation in order to practice the invention to the full scope of the claims.

4. Claims 1-4, 8, 11-21 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-4, 8, 11-21 and 44 are drawn to a composition comprising a ligand which binds to a surface antigen selected from the group consisting of an antibody, a fragment of an antibody and a synthetic peptide; an oligopeptide comprising a positively charged amino acid residue, not comprising more than two contiguous L-

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amino acids, said oligopeptide not binding to the surface antigen; and a label which is covalently bound to the oligopeptide. The specification teaches radio labeled SEQ ID NO:3 covalently bound to an anti-EGFRviii, L8A4, and radio labeled SEQ ID NO:3 covalently bound to a chimeric anti-EGFRviii, chL8A4. However, no disclosure, beyond the mere mention of antibody fragments and synthetic polypeptides is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only L8A4 and chL8A4, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

5. All other rejections and objections as recited in Paper No. 9 are withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

November 19, 2000

